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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/715,787	11/18/2003	Alexander Andrianov	533860-101	4559

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CARELLA, BYRNE, BAIN, GILFILLAN,
CECCHI, STEWART & OLSTEIN
5 Becker Farm Road
Roseland, NJ 07068

EXAMINER

LE, EMILY M

ART UNIT

PAPER NUMBER

1648

DATE MAILED: 03/31/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/715,787	Applicant(s) ANDRIANOV ET AL.	
	Examiner Emily Le	Art Unit 1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11/18/03, 12/12/03, 04/30/04, and 2/24/05.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-11 is/are pending in the application.
- 4a) Of the above claim(s) 8-11 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-7 is/are rejected.
- 7) ☒ Claim(s) 1-7 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 04/30/04 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>1/13/04</u> . | 6) <input type="checkbox"/> Other: _____ |

hcl

DETAILED ACTION

Election/Restrictions

1. Applicant's election without traverse of Group I, claims 1-7 in the reply filed on 02/24/2005 is acknowledged.

Status of Claims

2. Claims 1-11 are pending. Claims 8-11 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 02/24/2005. Claims 1-7 are under examination.

Specification

3. The drawings are objected to under 37 CFR 1.83(a) because they fail to show all three phases, in Figure 1, as described in the specification. Any structural detail that is essential for a proper understanding of the disclosed invention should be shown in the drawing. MPEP § 608.02(d). Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an

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application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Originally submitted Figure 1 indicates that the phase diagram represent three different phases. However, such detail is not readily apparent in the replacement sheet for Figure 1. Like the original submission, the replacement sheet indicates that three different phases are supposed to be present, see legend; however, a distinction between the precipitate and solution phases can be made.

Claim Objections

4. Claims 1-7 are objected to because of the following informalities: currently as written, it is not readily apparent that the recitation "or a salt thereof" is directed at the water-soluble polyphosphazene, organic amine or both. Appropriate correction is required.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claim 2 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claim is rendered indefinite for the recitation "wherein said...polyphosphazene and said organic amines are fed to the mixture". The recitation is indefinite because it is not clear as to what mixture in which polyphosphazene and organic amines are fed.

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. Claims 1-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Andrianov et al. in view of Pelta et al.

The claims are directed to a method of producing polyphosphazene microspheres comprising admixing an aqueous solution containing a water-soluble polyphosphazene and an aqueous solution containing organic amine or salt thereof, and allowing the reaction mixture to stand for an effective period of time to form thereby polyphosphazene microspheres. The claims further limit the polyphosphazene to poly[di(carboxylatophenoxy)phosphazene], the organic amine to spermine, and the microspheres have a diameter range of 1 μm to 10 μm . The claims additionally require that the polyphosphazene and the aqueous solution containing organic amine to be added over an extended period of time; the addition of water or buffer solution to stabilize the microspheres; and recovery of the polyphosphazene microspheres.

Andrianov et al. teaches a method of producing polyphosphazene microspheres comprising admixing an aqueous solution containing a water-soluble polyphosphazene and an aqueous solution, and allowing the reaction mixture to stand for an effective period of time to form thereby polyphosphazene microspheres. The polyphosphazene Andrianov et al. teaches is poly[di(carboxylatophenoxy)phosphazene]. Additionally, because

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Applicant does not specify the duration of time that is encompassed by the recitation "extended period of time", the period in which Andrianov et al. added polyphosphazene with the aqueous solution is considered to be encompassed by the limitation "extended period of time". Andrianov et al. also teaches stabilization of the microspheres by adding water and recovering of the polyphosphazene microspheres. [Section 2.4.] The microspheres of Andrianov et al. have diameters ranging from 1 μm to 10 μm . [First complete sentence, left column, page 112.] This range is the same as that instantly claimed.

Andrianov et al. does not teach the use of aqueous solution containing an organic amine or salt thereof, including spermine. Andrianov et al. uses sodium chloride as the coacervating agent. [Section 2.4.]

Pelta et al. teaches the use of polyamine, particularly spermine as a coacervating agent. [Title, abstract, and last full paragraph on page 5661.] Ergo, it would have been prima facie obvious for one of ordinary skill in the art at the time the invention was made to use one art-recognized coacervating agent in place of the other. One of ordinary skill in the art at the time the invention was made would have had a reasonable expectation of success for using spermine in place of sodium chloride because the art recognizes the suitability of the spermine as a coacervating agent.

Therefore, one of ordinary of ordinary skill in the art at the time the invention was made would have had a reasonable expectation of producing the claimed invention, absent unexpected results to the contrary.

Conclusion


9. No claim is allowed.

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10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Emily Le whose telephone number is (571) 272 0903. The examiner can normally be reached on Monday - Friday, 8 am - 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on (571) 272-0902. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



E. Le



Jeffrey S. Parkin, Ph.D.
Primary Patent Examiner
Art Unit 1648